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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,577	10/23/2003	Insu Lee	59150-8011.US01	9013

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PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER

HUYNH, CARLIC K

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,577	LEE ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/499,693.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :14 February 2005 and 07 October 2005.

DETAILED ACTION

Status of the Claims

1. Claims 4-12 are pending in the application, with claims 13-21 having been cancelled, in response to the restriction requirement submitted on November 15, 2006. Claims 1-3 have been cancelled in a Preliminary Amendment filed on October 23, 2003. Accordingly, claims 4-12 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election without traverse of the claims of Group I, namely claims 4-12, in the reply filed on December 15, 2006 is acknowledged.

Additionally, Applicant's election without traverse of learning faculty as the species of a brain function, in the reply filed on December 15, 2006 is acknowledged.

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on February 14, 2005 and October 7, 2005 is acknowledged.

Drawings

The drawings filed on October 23, 2003 are accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 4-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for strengthening learning faculty and memory, does not reasonably provide enablement for brain function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without *undue experimentation*. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). **Nature of the Invention:**

The rejected claim(s) is/are drawn to an invention which pertains to a method of strengthening a brain function selected from the group consisting of visual identification,

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recognition faculty, learning faculty, and memory.

(2). **State of the Prior Art:**

The skilled artisan would use docosahexaenoic acid (DHA) since DHA has been shown to play an important role in visual identification, recognition and learning faculty, and memory.

(3). **Relative Skill of Those in the Art:**

The relative skill of those in the arts of DHA and brain function strengthening is extremely high.

(4). **Predictability of the Art:**

DHA is also involved in the synthesis of cholesterol, blood clotting inhibition, aging, and cancer and is beneficial for the treatment of cardiovascular ailments, arthritis rheumatica and asthma and other lung diseases (page 1, paragraphs 2-3). Thus, the effects of DHA are highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). **Breadth of the Claims:**

The complex nature of the subject matter of this invention is greatly exacerbated by the

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breadth of the claims. The claims encompass the administration of linoleic acid and α -linolenic acid, the fatty acids from which DHA is derived, at various ratios of linoleic acid to α -linolenic acid to strengthen brain function.

(6). **Direction or Guidance Presented:**

The guidance given by the specification as to strengthening brain function by administering linoleic acid and α -linolenic acid at various ratios of linoleic acid to α -linolenic acid is limited.

The disclosure of strengthening learning ability and memory retention ability by administering linoleic acid and α -linolenic acid at various ratios of linoleic acid to α -linolenic acid is adequate (pages 7-10).

(7). **Working Examples:**

Rats were administered linoleic acid and α -linolenic acid at various ratios of linoleic acid to α -linolenic acid and then subjected to the Morris maze test to assess learning ability and memory retention ability (page 7). The results show the shorter the retention time, the higher the learning ability for a linoleic acid to α -linolenic acid ratio of 2 (figure 3A and B). The results also show the shorter the retention time, the higher the memory retention ability for a linoleic acid to α -linolenic acid ratio of 2 (figure 4A and B). Thus, the working examples show how to strengthen learning ability and memory retention ability, not how to strengthen brain function.

Note that lack of a working example to prevent, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

(8). **Quantity of Experimentation Necessary:**

The specification fails to provide sufficient support of strengthening brain function by administering linoleic acid and α -linolenic acid. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any drugs having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidance, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without *undue experimentation*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4-7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Spinner et al. (4,948,811) as evidenced by Rehkämper et al. (Journal of Dairy Science, 1998, vol. 81, pp. 1574-1580).

Spinner et al. teach triglyceride cooking/salad oil composition that can be used to promote growth and improve the development of visual acuity in humans and animals, wherein the composition is made up of linoleic and α -linolenic fatty acids in a weight ratio of linoleic and

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α -linolenic fatty acids at 2.0 (abstract; column 3, lines 5-7; column 4, lines 9-12; and column 4, lines 22-23).

Regarding "visual identification", as recited in instant claim 4, learning and memory is an inherent property. Spinner et al. do not specifically teach learning and memory but they teach a composition that includes linoleic and α -linolenic fatty acids that is used to promote growth and improve the development of visual acuity. Rehkämper et al. define visual acuity as the minimum size of an identifiable object (page 1574). One must learn what the object is in order to be able to identify it. Thus, visual acuity or visual identification cannot take place without learning and memory. Furthermore, a composition that can be used to improve visual acuity can in turn be used to improve learning and memory. Thus, it is reasonably expected that such a composition would include learning and memory as recited in instant claim 4. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stordy (6,150,411) in view of Spinner et al. (4,948,811).

Stordy teaches a method of treating dyslexia comprising administering DHA (column 2, lines 31-34). The DHA composition is made up of linoleic and α -linolenic fatty acids (column 1, lines 38-39). Stordy further teaches that dyslexia is a disorder manifested by difficulty in learning to read (column 1, lines 8-9).

Stordy also teaches that the daily dose of DHA is 20 mg to 10 g to children or adults (column 3, lines 22-23).

Additionally, Stordy teaches that for salad oils or for incorporation into any appropriate food material contain 5% by weight DHA (column 3, lines 28-30).

Stordy does not teach the weight ratio of linoleic to α -linolenic fatty acids.

Spinner et al. teach triglyceride cooking/salad oil composition that can be used to promote growth and improve the development of visual acuity, wherein the composition is made up of linoleic and α -linolenic fatty acids in a weight ratio of linoleic and α -linolenic fatty acids at 2.0 (abstract; column 3, lines 5-7; and column 4, lines 22-23).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the DHA compound of Stordy to have a weight ratio of linoleic and α -linolenic fatty acids at 2.0 because the compounds of Spinner et al. are made up linoleic and α -linolenic fatty acids in a weight ratio of 2.0 and according to Spinner et al., such compounds that are made up of linoleic and α -linolenic fatty acids have a weight ratio of 2.0.

The motivation to combine the compounds of Stordy to the compounds of Spinner et al. is that the compounds of Spinner et al. are compounds that are made up of linoleic and α -

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linolenic fatty acids and that such compounds that are made up of linoleic and α -linolenic fatty acids have a weight ratio of 2.0.

Regarding the daily dose of the composition, as recited in instant claims 8-9, it is noted that Stordy teach providing the DHA composition, a composition that contains linoleic and α -linolenic fatty acids, at 2 mg to 10 g, which closely meets the amounts of a daily dose set forth in instant claims 8-9. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of DHA provided in a composition, according to the guidance set forth in Stordy, to provide a composition having desired daily dose. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Conclusion


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh


SHENGJUN WANG
PRIMARY EXAMINER